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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,352	MATTSSON, JENS	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,4-7,10,11,14,15 and 17-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,4-7,10,11,14,15 and 17-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed April 14, 2004 has been received and entered. Claims 2-3, 8-9, 12-13, and 16 have been canceled, and new claims 25-27 have been added. Consequently claims 1, 4-7, 10-11, 14-15, and 17-27 are pending in the instant application.

Claim Rejections - 35 USC § 101

1. The rejection of claims 6 and 10-11 under 35 USC 101 is withdrawn in view of Applicants amendment.

2. The rejection of claims 12-13, and 16-17 as providing for the use of a protein, but not setting forth any steps involved in the method/process is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

3. The rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "essentially/substantially identical/preserved" is maintained.

It is noted that this rejection is withdrawn from claims 1 and 5 in view of Applicants amendment.

However, claims 14-15 still recite "spatial arrangement of one or more biologically active regions remain ***substantially preserved***." (Emphasis added).

Applicants have not provided any arguments concerning this phrase. The term simply does not allow one of skill in the art to determine at what point a molecule is substantially preserved versus a point at which it is no longer substantially preserved, thereby allowing one of skill in the art to determine if the molecule is encompassed within the scope of the claim. Accordingly this rejection is maintained for reasons of record.

4. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being vague and indefinite for the recitation of "stringent conditions" is withdrawn in view of Applicants amendment.

5. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of the phrase "similar biological activities" is withdrawn in view of the cancellation of said claim.

6. The rejection of claims 14-15 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of the phrase "analogues that mimic" at least a part of the structure of the protein is withdrawn in view of Applicants amendment.

7. The rejection of claims 1, 4-7, 10-11, 14-15, 17-24 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Additionally this rejection is applied to newly added claims 25-27.

Applicants are asserting that at page 10, line 1, the specification notes that the invention relates to a protein comprised of at least 83 amino acids of SEQ ID NO: 2. Applicants further assert that the Figures show the extent of the recombinant protein according to the invention.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, this is not a new matter rejection. Reciting support within the specification for the claimed language is not being questioned. However, Applicants specification describes a single protein fragment (SEQ ID NO: 2) and based upon that single species attempts to claim a genus of proteins i.e., any protein "comprising" at least 83 amino acids of SEQ ID NO: 2. It is these structural variants which have not been adequately described by the specification. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 2 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the

claimed genus. Furthermore, since SEQ ID NO: 2 is a fragment of a full length protein, the written description is only commensurate in scope with this fragment, thus the claims are only adequately described for "consisting of" the identified fragment, since additionally amino acids on the N or C terminus will have a profound effect on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

8. The rejection of claims 19-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition consisting of SEQ ID NO: 2 does not reasonably provide enablement for vaccines comprising SEQ ID NO: 2 is maintained.

It is noted that this rejection has been withdrawn from claims 16-18 in view of Applicants amendment to recite "immunogenic preparations."

Applicants are asserting that the claimed invention is fully supported by the present disclosure.

Applicants arguments have been fully considered but are not found to be fully persuasive.

As set forth previously by Plotkin et al, those of skill in the art recognize that it is unpredictable whether a single protein derived from a pathogen will elicit protective immunity. This is the type of immunity required by Applicants claims 19-21, i.e., for the ***prevention*** of Sarcoptes mange or scabies. Thus, Factors 1, 4, 5 and 7 are all addressed by this teaching. Furthermore, Applicants specification provides no working examples of any successful prevention (Factors 1 and 3).

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

The specification provides insufficient guidance of how to use the claimed polypeptides as a pharmaceutical for the prevention of disease. It is well recognized in the art that it is unclear

whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A et al.,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen."

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the proteins encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

9. The rejection of claim 8 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant host cells, does not reasonably provide enablement for all recombinant cells is maintained as applied to newly added claim 25. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants are asserting that any assertion that the enabling disclosure is not commensurate in scope for the protection sought must be supported by evidence or reasoning substantiating a doubt so expressed.

Applicants arguments have been fully considered but are not found to be fully persuasive.

As set forth previously, Applicant's specification demonstrates the transformation of heterologous DNA into *E. coli*. However, this does not provide enablement for all transgenic host cells. Transgenic host cells can include human cell lines. Applicant's have provided no guidance or working examples of any transformed cell line other than a prokaryotic *E. coli* strain.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Thus, Applicant's have not provided sufficient guidance to enable one skilled in the art to make and use any transgenic cell in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and

improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

As a suggestion, amendment of the claims to recite "An isolated host cell comprising..." will be sufficient to overcome this rejection.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Birkett is maintained.

Applicants are asserting that Birkett et al use random hexamers and random priming and labeling procedures where one must rely on relatively low annealing temperatures. Applicants assert that these procedures would fall outside the scope of the "stringent conditions" recited in claim 6. Applicants further assert that one of

ordinary skill in the art would understand that the word stringent would not be connected to the buffers and temperature conditions that are used at reactions with hexamers.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Birkett et al use random hexamers and random priming and labeling procedures where one must rely on relatively low annealing temperatures, which fall outside the scope of the "stringent conditions" recited in claim 6. However, since the probe disclosed by Birkett will be an "exact" match for 6 consecutive nucleotides it will hybridize under the conditions recited in claim 6. Stringent conditions prevent molecules with mismatches from being able to hybridize, given that there will be zero mismatches among some of the probes, the conditions simply do not exclude the probes disclosed by Birkett.

Finally Applicants assert that one of ordinary skill in the art would understand that the word stringent would not be connected to the buffers and temperature conditions that are used at reactions with hexamers. However, the question remains is the isolated nucleic acid sequence disclosed by Birkett encompassed within the claim? Given that it is an isolated nucleic acid sequence which contains zero mismatches with the DNA sequence of the instant invention, it is deemed to meet each and every limitation of the claims.

The claims are drawn to a nucleic acid which hybridizes specifically under stringent conditions to a nucleic acid according to claim 4.

Birkett et al (U.S. Patent Number 5,302,527) disclose of random priming with a mixed hexamer oligonucleotide kit (Multiprime Kit, Amersham). (See column 15 lines 25-30).

In view that Birkett disclose of oligomers containing every possible combination of nucleotides for 6 mers, and that these sequences will inherently hybridize to DNA encoding the protein of SEQ ID NO: 2 under the recited conditions, the disclosure of Birkett et al is deemed to anticipate the claimed invention.

For reasons of record as well as the reasons set forth above this rejection is maintained.

11. The rejection of claims 14-15 under 35 U.S.C. 102(e) as being anticipated by Hsu is maintained.

Applicants are asserting that claims 14-15 relate to a method for screening proteins or protein analogues that resemble at least a part of the structure of the protein according to claim 1. Applicants assert that Hsu disclose of screening analogues for the capacity to mimic the activity of a CAIP-like polypeptide. Applicants conclude that CAIP proteins disclosed by Hsu are quite different from the proteins of the application.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that claims 14-15 relate to a method for screening proteins or protein analogues that resemble at least a part of the structure of the protein according to claim 1. However, there is no requirement as to how big or what activity or

anything else for that matter, that the analogue must retain. Given that there are only 20 amino acids in any single protein and that the CAIP analogues and the protein of the instant invention share many of these same amino acids, the disclosure of Hsu is reasonably deemed to be an "analogue" of the protein of the instant invention.

Finally Applicants conclude that CAIP proteins disclosed by Hsu are quite different from the proteins of the application. However, Applicants are respectfully directed back to the claims. There is simply no limitation in the first place about the structure of the protein. Rather the claims are directed to "analogues" and further selecting an analogue wherein the three-dimensional configuration and spatial arrangement of one or more biologically active regions remain ***substantially preserved***. Accordingly, each and every limitation has been fully disclosed by Hsu.

The claims are directed to a method for screening protein or peptide analogues according to claim 1, which comprises the steps of producing a multiplicity of analogue structures and selecting an analogue structure, wherein the three dimensional configuration and spatial arrangement of one or more biologically active regions remain substantially preserved.

Hsu (US Patent Number 6,171,800) disclose of evaluating compounds for the ability to inhibit or promote an interaction with a CAIP like family polypeptide. (See column 9).

In view that Hsu disclose of screening analogues for the ability to mimic the activity of a CAIP like polypeptide, the disclosure of Hsu is deemed to anticipate the claimed invention. It is noted that the claims further recite a "three-dimensional

configuration and spatial arrangement... substantially preserved." Given that the degree of preservation is not set forth, the CAIP like polypeptides are deemed to be "substantially preserved."

For reasons of record as well as the reasons set forth above this rejection is maintained.

The following new grounds of rejection are applied to the amended claims:

Claim Rejections - 35 USC § 112

12. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 6 recites stringent conditions of "less than about 10 M Na ion." However, Applicants specification provides no support for this range of Na ion concentration. Applicants specification on page 4 provides for stringent conditions to include less than about 1.0 M Na ion concentration. Applicant is required to demonstrate clear support for the newly added limitation, or cancel the newly added material.

13. Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "A method for screening protein or peptide analogues according to claim 1." However claim 1 is not a method claim nor does it recite any peptide analogues.

Appropriate correction is required.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
June 23, 2004